

# DIAGNOSTIC EXPERIENCE



Let Your Data Grow<sup>®</sup>

Stat One has been involved in study design and data analysis for a variety of diagnostics products that were cleared by the FDA. Areas of our experience include studies involving ultrasound, light imaging, mammography, tomography, contrast and fluorescing agents, cardiac stress agents, assay methods, and IVDs. Activities completed range from protocol development and sample size work to analysis of MRMC studies, ROC curves and AUC; risk assessment, and test operating characteristics such as sensitivity and specificity.

Stat One has provided support for and participated in numerous FDA meetings.